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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Henry William LUPTON

Appln. No.: 10/076,369 Group Art Unit: Not Assigned

Confirmation No.: 1502 Examiner: Not Assigned

Filed: February 19, 2002

For: A CATHETER AND STENT

SUBMISSION OF PRIORITY DOCUMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith is a certified copy of the priority document on which a claim to priority was made under 35 U.S.C. § 119. **The Examiner is respectfully requested to acknowledge receipt of said priority document.**

Respectfully submitted,

John Callahan

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Date: March 19, 2002

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Signed R. Mahoney

Dated 21 February 2002

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20FEB01 E607342-9 D00041
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1. Your reference — SAH01532GB

2. Patent application number *(The Patent Office will fill in this part)* — **0104069.0**

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Biocompatibles Limited
Chapman House
Farnham Business Park
Weydon Lane, Farnham
Surrey GU9 8QL

Patents ADP number *(if you know it)* 05737515003

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — A Catheter

5. Name of your agent *(if you have one)* — Gill Jennings & Every

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Broadgate House
7 Eldon Street
London
EC2M 7LH

Patents ADP number *(if you know it)* — 745002 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

19 FEB 2001

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	5
Claim *(s)*	1
Abstract	1
Drawing *(s)*	5 + 5

10. If you are also filing any of the following, state how many against each item.

Priority documents	0
Translations of priority documents	0
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	0
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	0
Any other documents *(please specify)*	NO

11. For the applicant
Gill Jennings & Every

I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 19 February 2001

12. Name and daytime telephone number of person to contact in the United Kingdom

HALEY, Stephen
020 7377 1377

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A CATHETER

This invention relates to catheters for insertion into the lumen of a human or animal body. The invention has particular benefits in relation to balloon catheters, particularly of the type used for the delivery of medical devices such as stents, but is not explicitly limited thereto.

Catheters are usually inserted into a body lumen over a guidewire and into a position in which a treatment can be performed or a device placed on the catheter can be delivered. Because of the need for the catheter to pass through narrow lumens there are severe restrictions in terms of maximum catheter diameter. Also because such catheters must be lengthy they need to be formed from resilient material that is resistant to unwanted axial twisting whilst still being extremely flexible so that they can pass through the curves of a body lumen. This applies considerable constraints in terms of the materials that may be employed in catheter construction. It also constrains the ability to provide appropriate rigidity in the catheter if a hollow lumen catheter is necessary and also makes it difficult to provide appropriate support for any device to be delivered in the particular situation when the catheter is designed to deliver a device such as a stent. This is a particular problem at the catheter tip, where it may be necessary to provide an expansion balloon as well as support for a device such as a stent, resulting in a region which is built up with respect to the remainder of the catheter yet for which it would still be desirable to provide appropriate flexibility to enable good manoeuverability for the catheter as a whole. For example, catheters are known for which an expansion balloon is provided toward their distal end, the expansion balloon supporting a stent which is deployed by expansion of the balloon once the balloon region has been placed in the desired position in a body. So that the stent can be

retained properly until deployment such catheters often require a built-up region underneath the balloon and the stent so that the stent is held on the catheter with sufficient retention force. Regardless of the material from which the built-up region is made, this results in a thickening of the tip region of the catheter and naturally stiffens any support lumen beneath the built-up region.

The present invention seeks to provide a catheter with a more flexible tip that overcomes some of the above problems.

According to the present invention there is provided a catheter for insertion into the lumen of a human or animal body, the catheter having an elongate body with proximal and distal ends, the body comprising a hollow tubular member, wherein at least one section of the walls of the tubular member in the distal region is corrugated.

The corrugation may be provided by a series of circular indentations forming ribs therebetween. Alternatively, the corrugation may be provided by a single spiral indentation along the wall. If a series of circular indentations are provided then slots may be cut in the ribs that are formed to provide additional flexibility in the corrugations.

Wire may be inserted into the corrugated section to provide a region of increased radiopacity.

The corrugated section may have a balloon formed over it.

A support region may be formed over the corrugated section in order to provide supporting retention for a stent placed there over in use.

The corrugated section of the catheter of the present invention has flexibility to a section of a catheter which is usually rigid with respect to other portions of the body of the catheter. It does this while still retaining rigidity to reduce the likelihood of unwanted kinking in the tubular body of the catheter. However, it still provides the ability for additional support structures and

a balloon configuration to be provided over it so that the overall functionality and retention characteristics of the catheter can be retained.

Examples of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a schematic partial cross-sectional view of a prior art catheter;

Figure 2 is a schematic side view of a corrugated section in an example catheter according to the invention both in a compressed and a stretched state;

Figures 3a to 3g show alternative example corrugation configurations that may be employed in the present invention;

Figure 4 shows a further example of a corrugation section in accordance with the present invention; and

Figure 5 shows an example of the present invention with radiopaque wire inserted therein.

Referring to figure 1, a known catheter 1 has a main body 2 with a distal end 3 and a proximal end 4. In use, the catheter 1 is guided over a guidewire 5 so that the distal end 3 can be positioned in a desired location within a body lumen (not shown). The prior art catheter 1 that is shown is of the balloon type and has a balloon 6 at the distal end 3 which can be inflated in use by the pumping of fluid (not shown) from the proximal end 4 via a lumen 7 which opens in the balloon 6. The distal region 3 has a support structure 8 formed on the tubular member 9 which forms the main body of the catheter 1 of which surrounds the guidewire 5 in use. The support section 8, shown only partially in figure 1, provides a raised region when the balloon 6 is compressed over it so that a stent (not shown) positioned over the balloon 6 can be retained on the catheter 1 without fear of it falling off and without damage to the stent when it is compressed onto the balloon 6.

Figure 2 shows a portion of a catheter according to the present invention. Components which correspond to those shown in the prior art catheter of figure 1 are numbered identically.

The two examples shown in figure 2 show a tubular member 9 from the distal portion of a catheter according to the present invention which may be of the balloon type shown in figure 1 and which may be configured to deliver a stent. The tubular member 9 has a corrugated section 10 which can be compressed and stretched as shown in figure 2. It will be appreciated that the corrugated section 10 provides resistance to kinking but increases the flexibility of the tubular member 9 when it is bent so that its axis is not straight. Figures 3a to 3g show examples of corrugation types that may be provided with the present invention. Figures 3a to 3d show ribs 11 which vary in number and thickness in the axial direction and which define slots 12 which are also of varying width and thickness in the axial direction. The example corrugated section 10 of figure 3a has ribs 11 which stand proud of the outer diameter of the tubular member 9 to provide a support region similar of function to that of support region 8 shown in figure 1. The relative thicknesses of the ribs 11 and slots 12 can be chosen dependent upon the level of flexibility and kink-resistance that is required, as well as the level of retaining force that may be required to be applied to a stent positioned thereover in use.

Figures 3e and 3f show alternative configuration which again have ribs 11 and slots 12, but which have additional slots 13 cut within at least some of the ribs 11 to provide additional flexibility and also to provide the strain relief during flexing of the tubular member 9. The example of figure 3f again has ribs 11 which are proud of the outer diameter of the tubular member 9.

The example of figure 3g again has a corrugated region 10 which is formed from a single spiral rib 11 which

defines a spiral slot 12. This example may be adapted such that the rib 11 stands proud of the outer diameter of the tubular member 9 as with other examples.

Figure 4 shows a further example of the invention in which plural corrugated sections 10 are provided. In this example any of the configurations shown in figures 2 and 3 may be employed for each of the corrugated sections 10 and may be mixed to provide optimum flexibility and retaining force as required.

Figure 5 shows a further example of the present invention in which the corrugated section 10 has radiopaque filaments 13 embedded therein. These may be embedded either in the ribs 11 or the slots 12. Again, the corrugated section 10 may be of the construction of any of the preceding examples. The present invention lends itself particularly to the employment of such radiopaque filaments 13, as these can be retained readily in the ribs 11 or slots 12 without adverse effect to the overall flexibility of the member 9.

CLAIMS

1. A catheter for insertion into the lumen of a human or animal body, the catheter having an elongate body with proximal and distal ends, the body comprising a hollow tubular member, wherein at least one section of the walls of the tubular member in the distal region is corrugated.

2. A catheter according to claim 1, wherein the corrugation is provided by a series of circular indentations forming ribs therebetween.

3. A catheter according to claim 2, wherein slots are cut in the ribs that are formed to provide additional flexibility in the corrugations.

4. A catheter according to claim 1, wherein the corrugation is provided a single spiral indentation along the wall.

5. A catheter according to any preceding claim, wherein wire inserted into the corrugated section to provide a region of increased radiopacity.

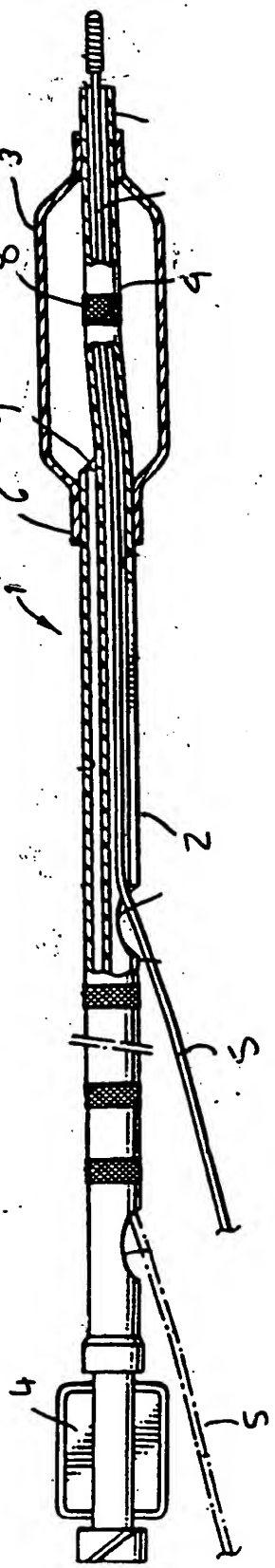
6. A catheter according to any preceding claim, wherein the corrugated section has a balloon formed over it.

7. A catheter according to any preceding claim, wherein a support region is formed over the corrugated section in order to provide supporting retention for a stent placed there over in use.

ABSTRACT

A catheter for insertion into the lumen of a human or animal body. The catheter has an elongate body with proximal and distal ends, the body comprising a hollow tubular member. At least one section of the walls of the tubular member in the distal region is corrugated.

FIG. 1



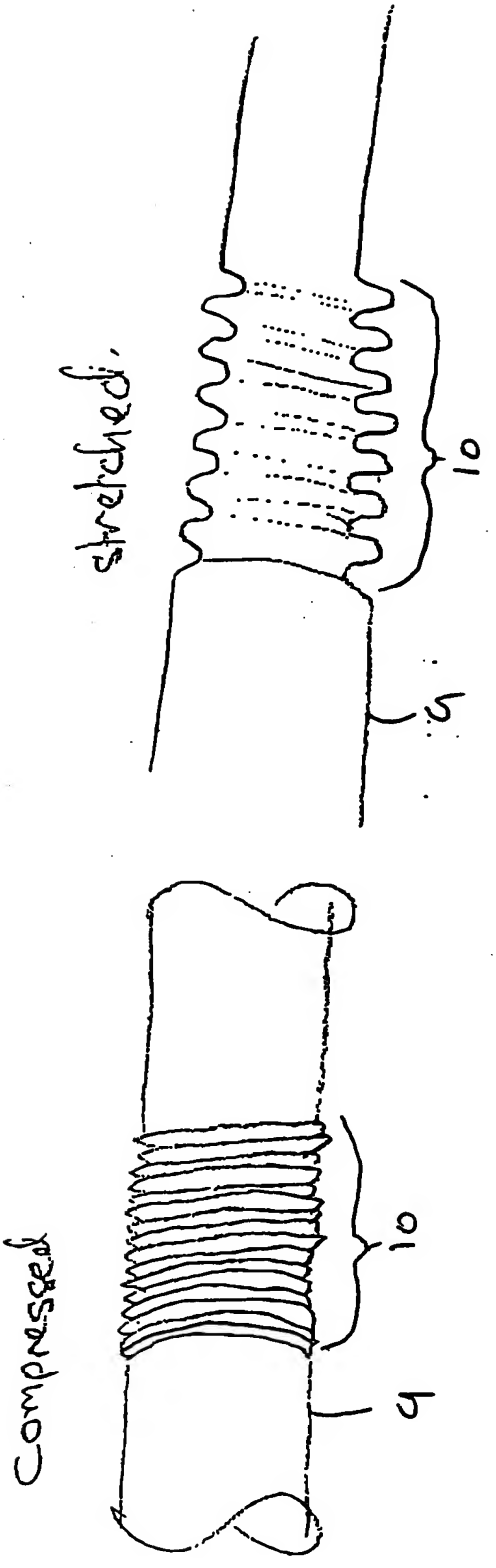


Fig. 2

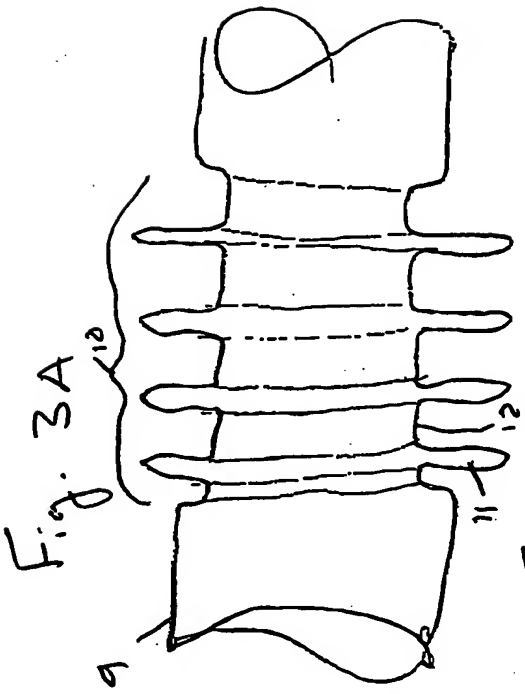


Fig. 3A
12
11
6

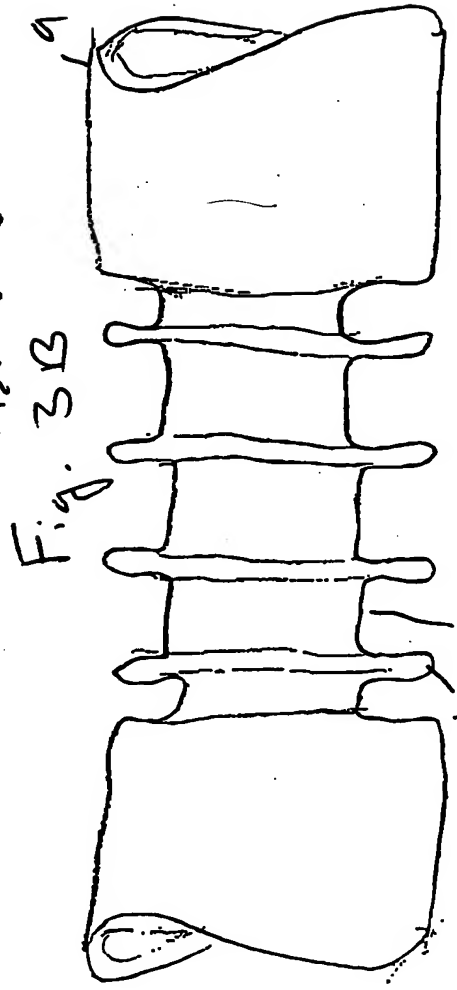


Fig. 3B
6
12
11

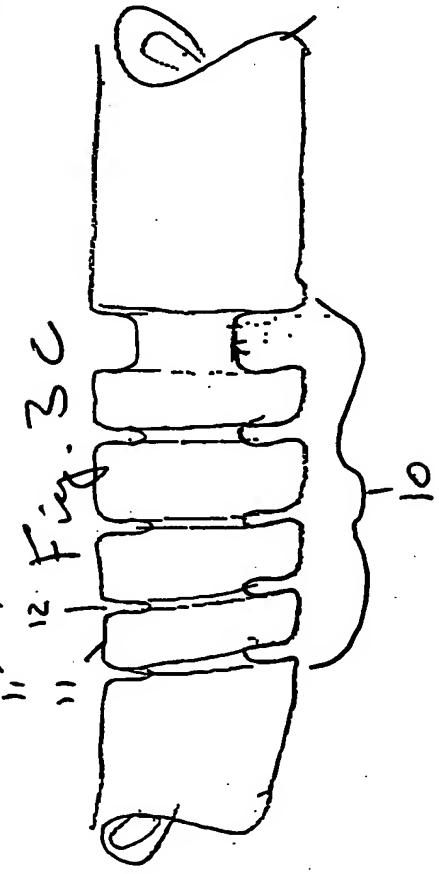


Fig. 3C
10
12
11

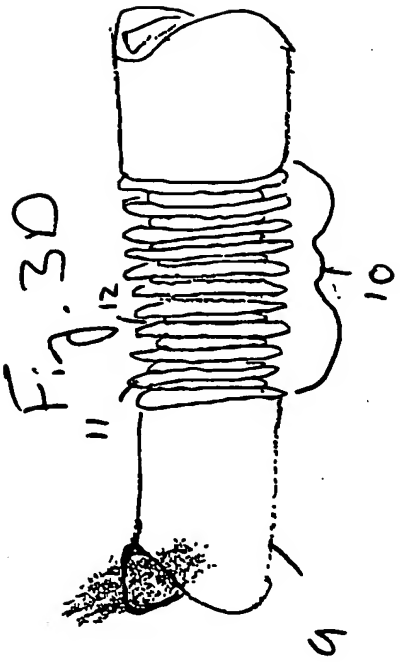


Fig. 3D
10
12
11
6

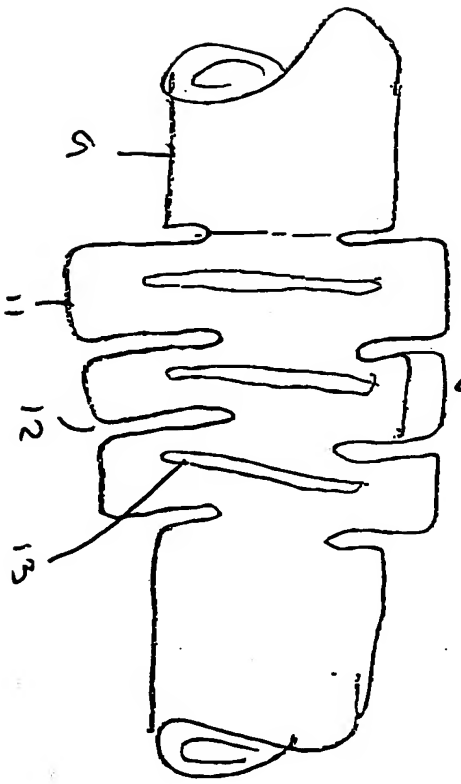


Fig. 3F

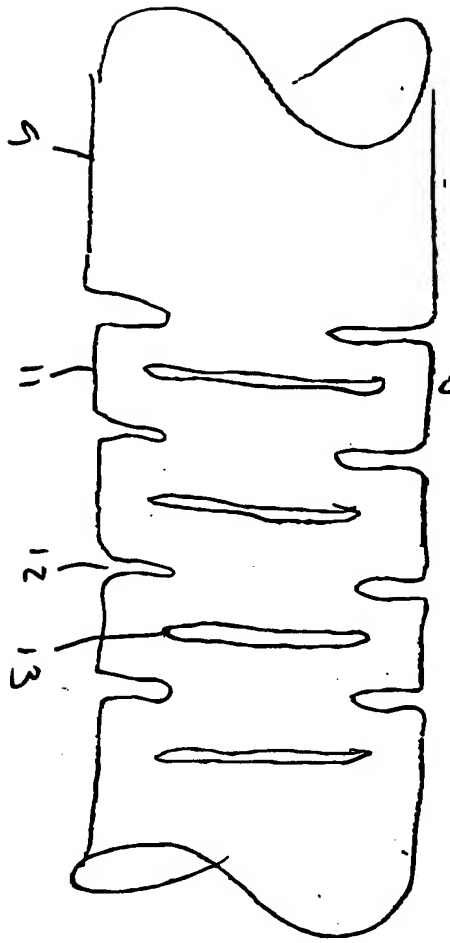


Fig 3E

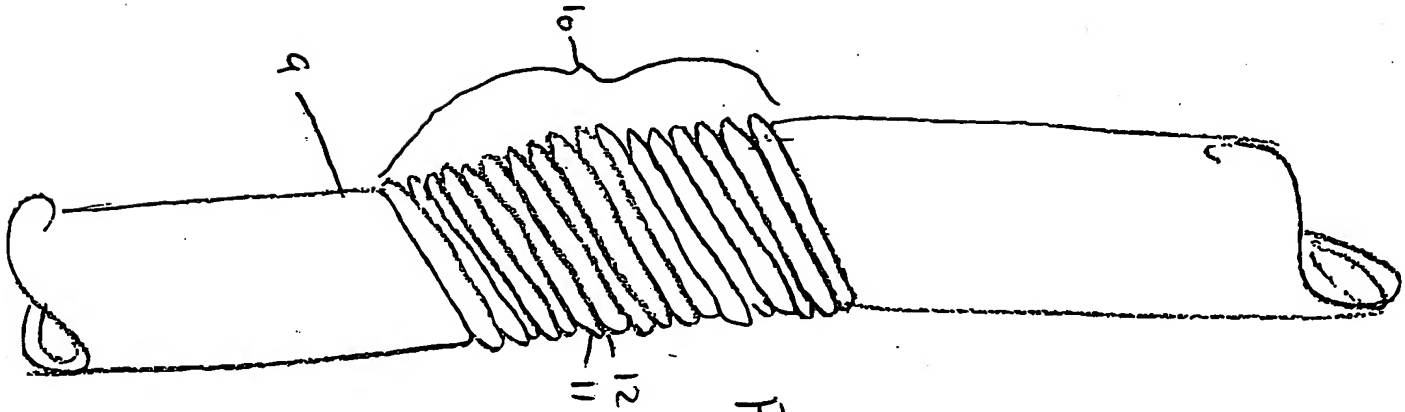


Fig 3G

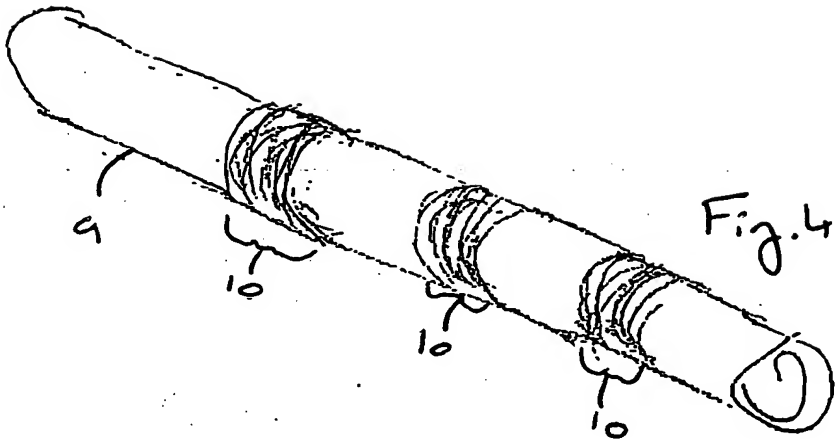


Fig. 4

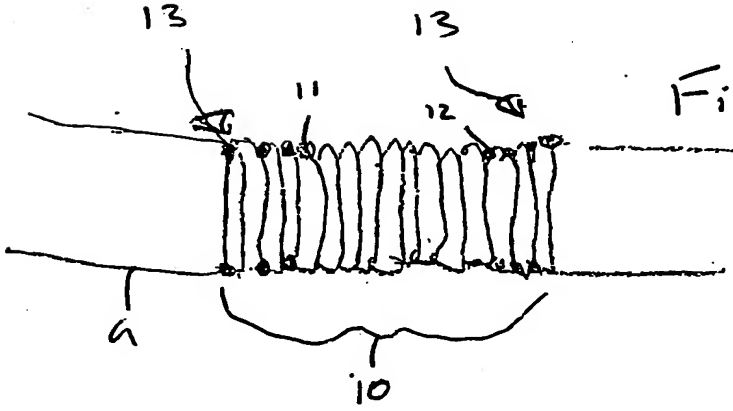


Fig. 5